IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES AG and EDWARDS LIFESCIENCES LLC, Plaintiffs, v. COREVALVE, INC. and MEDTRONIC COREVALVE LLC, Defendants.	)	C.A. No. 08-91 (GMS) **REDACTED - PUBLIC VERSION**

EDWARDS' OPENING BRIEF IN SUPPORT OF ITS MOTION FOR A PERMANENT INJUNCTION

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I. INTRODUCTION

This is no ordinary injunction motion. The continued success and growth of Edwards[1] depends on an injunction against willful infringer, and direct competitor, Medtronic CoreValve.[2] The record is clear. Medtronic CoreValve made a calculated, strategic decision to continue to infringe the '552 Patent[3] after the April 1, 2010 jury verdict. And it continues to do so today. Medtronic CoreValve, with a complete disregard for judicial authority or the patent system, not only intends to continue to infringe, but to [redacted]. Edwards needs an injunction to avoid the irreparable harm such [redacted] will cause, the extent of which is immeasurable.

The transcatheter heart valve ("THV") business is the lifeblood of Edwards. Edwards invested heavily in THVs, [redacted], including purchasing the revolutionary '552 Patent and developing its SAPIEN product line. Medtronic CoreValve, on the other hand, made its advances by willfully infringing the '552 Patent, which it acknowledged is a "strong" patent. It marched on despite an express warning from Edwards. Medtronic CoreValve began as CoreValve, Inc. and was purchased during this lawsuit by the largest standalone medical device company in the world – Medtronic, Inc. ("Medtronic"). THVs account for only a small fraction of Medtronic's revenue. Medtronic CoreValve has and will continue to leverage Medtronic's size and market power to capture market share from Edwards. From the outset, Medtronic bragged that its "scale" would "accelerate" use of the infringing devices.

Medtronic CoreValve's conduct in Europe provides empirical proof of what will happen

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1 Edwards Lifesciences AG and Edwards Lifesciences LLC (collectively "Edwards").
2 CoreValve, Inc. and Medtronic CoreValve LLC (collectively "Medtronic CoreValve").
3 Andersen et al. U.S. Patent 5,411,552 ("the '552 Patent").

in developing markets abroad and in the U.S. absent an injunction. In Europe, Medtronic CoreValve trained doctors to use its infringing, U.S.-made ReValving products, and established accounts at hospitals. Edwards lost significant sales, market share, goodwill, and reputation as the THV innovator. Just a week after the verdict, Medtronic's CEO appeared on CNBC and touted its willfully infringing product as Medtronic's "innovation." These harms continue today, as those doctors and hospitals stick to what Medtronic CoreValve taught them – the ReValving products. Medtronic CoreValve is employing this approach with [redacted] ReValving products in [redacted]. And it is pursuing the same strategy in the [redacted].

Despite years of misleading statements about moving infringing activities abroad, Medtronic CoreValve continues its willful infringement in the U.S. today. The reason is simple: to increase its profits. Medtronic CoreValve could and should have moved to Mexico, and quickly. It made a calculated decision not to. Even if it had moved to Mexico, under governing authorities cessation of infringement is no reason to withhold injunctive relief.

The patent system – even post-*eBay* – is intended to protect innovation and patentees in the U.S. The only proper remedy for Edwards is an injunction.

II. NATURE AND STAGE OF THE PROCEEDINGS

The jury found Medtronic CoreValve to be a literal, willful infringer of Claim 1 of the '552 Patent based on its manufacture of ReValving products in Irvine, California. [D.I. 313 at 2-3]. The jury rejected Medtronic CoreValve's non-enablement defense and awarded about $74 million in damages. [*Id.* at 4-5]. After trial, the Court denied Medtronic CoreValve's motions for JMOL and a new trial. [D.I. 429]. The Court denied Edwards' motion for an injunction based on the record before it. [*Id.*].

Medtronic CoreValve appealed the verdict, and Edwards cross-appealed, *inter alia*, the denial of an injunction. [D.I. 431, 435]. The Federal Circuit affirmed the verdict and vacated the denial of an injunction. *Edwards Lifesciences AG* v. *CoreValve, Inc.*, 699 F.3d 1305, 1315-16 (Fed. Cir. 2012). The Federal Circuit remanded the case for, *inter alia*, consideration of an injunction in light of ensuing events. *Id.* On February 11, 2013, the Federal Circuit issued the mandate, having denied Medtronic CoreValve's petition for rehearing en banc and motion to stay the mandate. [D.I. 448].

III. SUMMARY OF ARGUMENT

1. An injunction is warranted under 35 U.S.C. § 283. Edwards "practices its invention and is a direct market competitor" with Medtronic CoreValve. *Edwards*, 699 F.3d at 1315. Since the April 1, 2010 verdict, Medtronic CoreValve chose to continue to willfully infringe the '552 Patent. Only an injunction will change its behavior.

2. Critically, absent an injunction, Medtronic CoreValve plans a [redacted]. Edwards and Medtronic CoreValve will be the only competitors in the U.S. market during the life of the '552 Patent.

3. THV is Edwards' "most important growth driver."

4. Allowing Medtronic CoreValve to launch its head-to-head competing products in the U.S., in the face of being an adjudicated willful infringer, will cripple Edwards, as described herein.

5. Equity sets forth the relevant four-factor test for an injunction: (1) irreparable harm, (2) inadequacy of remedies at law, (3) balance of hardships, and (4) the public interest. *eBay Inc.* v. *MercExchange, LLC*, 547 U.S. 388, 391-92 (2006). Post-*eBay*, injunctive relief continues to be an appropriate remedy to stop willful infringement. *Presidio Components, Inc.* v. *Am. Tech. Ceramics Corp.*, 702 F.3d 1351, 1362-63 (Fed. Cir. 2012).

6. Edwards has suffered and will suffer irreparable harm. The parties' "[d]irect competition in the same market" strongly suggests "the potential for irreparable harm." *Id.* at 1363. Edwards continues to suffer lost sales and loss of market share, both of which "squarely support[] a finding of irreparable harm." *Id.*; *Robert Bosch LLC* v. *Pylon Mfg. Corp.*, 659 F.3d 1142, 1152 (Fed. Cir. 2011). Edwards continues to suffer price erosion due to Medtronic CoreValve's cheaper infringing device. And Edwards continues to lose opportunities to train doctors and establish hospital accounts, thus losing access to potential customers for years into the future. *Robert Bosch*, 659 F.3d at 1152 ("loss of . . . access to potential customers" supports irreparable harm finding); *i4i Ltd. P'ship* v. *Microsoft Corp.*, 598 F.3d 831, 862 (Fed. Cir. 2010) (affirming injunction where "the infringing acts significantly change[d] the relevant market").

7. Edwards cannot protect its right to exclude with a damages award. Absent an injunction, Edwards' only THV competitor in the U.S. will continue to infringe the '552 Patent, and thus a damages award will not be "as practical and efficient to the ends of justice and its prompt administration as the remedy in equity." *Acumed LLC* v. *Stryker Corp.*, No. 04-CV-513-BR, 2007 WL 4180682, at *5 (D. Or. Nov. 20, 2007) (granting injunction), *aff'd*, 551 F.3d 1323 (Fed. Cir. 2008). Further, monetary damages will not compensate Edwards for unquantifiable losses, such as loss of market share, brand recognition, and customer goodwill. *Broadcom Corp.* v. *Qualcomm Inc.*, 543 F.3d 683, 703 (Fed. Cir. 2008) ("[D]ifficulty in estimating monetary damages reinforces the inadequacy of a remedy at law."); *i4i*, 598 F.3d at 862.

8. Requiring Edwards "to compete against its own patented invention," with the resultant irreparable harms, places "a substantial hardship" on Edwards. *Robert Bosch*, 659 F.3d at 1156. In contrast, there is no cognizable hardship to Medtronic CoreValve. Medtronic CoreValve made a [redacted] to stay in the U.S. and increase its profits. It "cannot be

heard to complain" if it is enjoined from continuing to infringe. *Acumed*, 551 F.3d at 1330.

9. Edwards' proposed injunction protects the public interest. The FDA found Edwards' SAPIEN products to be safe and effective. Edwards' proposed order, which carves out the few patients it cannot treat, "strikes a workable balance between protecting the patentee's rights and protecting the public from the injunction's adverse effects." *i4i*, 598 F.3d at 863.

IV. STATEMENT OF FACTS

A. Trial and Appeal

1. Medtronic CoreValve Is a Willful, Literal Infringer

In 2010, after an eight-day trial, the jury found that Medtronic CoreValve's ReValving products literally infringe Claim 1 of the '552 Patent under 35 U.S.C. § 271(a), and that the infringement was willful. [D.I. 313 at 2-3]. The jury rejected Medtronic CoreValve's only invalidity defense (non-enablement) and awarded Edwards $72,645,555 in lost profits and $1,284,861 in reasonable royalties. [*Id.* at 4]. Judgment was entered on May 4, 2010. [D.I. 324]. Medtronic CoreValve's JMOL and new trial motions were denied.[4] [D.I. 429].

2. The Court Denied Edwards' Motion for a Permanent Injunction, Relying on Medtronic CoreValve's Representations About Moving Its Manufacturing Operations to Mexico

On May 28, 2010, Edwards moved for a permanent injunction. [D.I. 357]. In opposition, Medtronic CoreValve stated it [redacted] [D.I. 392 at 6]. In public statements, Medtronic CoreValve was similarly explicit: "In the event of a U.S. injunction, Medtronic has manufacturing capabilities for CoreValve products outside the United

[4] The '552 Patent has been twice upheld in post-trial reexaminations. [Declaration of Christopher Terranova ("Decl."), Exs. U, V]. It has also received two interim patent term extensions. [*Id.*, Exs. R, S]. The FDA-calculated regulatory review period would result in an extension to March 22, 2016. [*Id.*, Ex. T].

States." [D.I. 358, Egan Decl., Ex. 21]. Relying on Medtronic CoreValve's representations, the Court denied Edwards' injunction motion on February 7, 2011. [D.I. 429 at 27-29].

3. On Appeal, Medtronic CoreValve Admitted [redacted]

Medtronic CoreValve's representations that it was moving abroad were subject to no discovery before the Court decided Edwards' injunction motion. Like the Court, Edwards relied on Medtronic CoreValve's post-trial press releases, and declarations of employees that Edwards had no opportunity to cross-examine. [D.I. 358, Egan Decl., Ex. 21; D.I. 393, A415-667].

Only after the Court denied Edwards' motion for an injunction did it become clear that Medtronic CoreValve never stopped making infringing THVs in the U.S. [redacted] [D.I. 439, Ex. 4a].

On appeal, Medtronic CoreValve acknowledged that [redacted] [Decl., Ex. A at 43]. Undeterred by the jury verdict, the judgment, and the representations it made to this Court, Medtronic CoreValve chose to continue willfully infringing the '552 Patent.

4. The Federal Circuit Affirmed the Verdict and Remanded for, *Inter Alia*, Consideration of an Injunction

The Federal Circuit affirmed the verdict of willful infringement and rejected Medtronic CoreValve's attack on the '552 Patent's validity. *Edwards*, 699 F.3d at 1308-13. With respect to the denial of an injunction, the Federal Circuit noted that the Court's decision was based in "significant" part on "CoreValve's statements that it was immediately moving [its] manufacturing operation to Mexico, and thus that infringement would terminate." *Id.* at 1315. On appeal, however, "CoreValve [did] not deny[] that CoreValve never stopped its infringing

manufacture." *Id.* "Whether or not that representation was known to be false when made, the situation before us reflects, at least, changed circumstances." *Id.* (emphasis added). The Federal Circuit vacated the denial of the injunction and remanded the case to this Court "for consideration in light of ensuing events and any other relevant factors." *Id.* at 1315-16. The Federal Circuit did so because "district courts are in the best position to fashion an injunction tailored to prevent or remedy infringement." *Id.* at 1315 (quotations omitted).

B. Edwards' Lifeblood is THV

Edwards is a heart valve company. Heart valves account for over 70% of Edwards' business, compared to less than 7% of Medtronic's business. [Decl., Ex. N at 34 (Structural Heart 2012 net sales); Ex. O at 26 (2012 net sales)]. In the early 2000s, Edwards determined that the future of the heart valves lay in THVs, which could be delivered with much less trauma to the patient than surgical valves. Edwards invested heavily in THVs, [redacted], including buying the revolutionary THV '552 Patent. [Declaration of Larry Wood ("Wood Decl.") ¶¶ 6-9, 15]. Today, Edwards' lifeblood is THV. In 2012, Edwards' THV net sales increased 65.4%; the next highest product line increase was 0.4%. [Decl., Ex. O at 26]. Financial analysts have taken note, reporting that "almost all of the attention focused on [Edwards] today is due to its ongoing pioneering role in the development [of] transcatheter heart valve technology." [Decl., Ex. L at 2 (Feb. 5, 2013 Bank of America Report), Ex. M at 9 (valuing Edwards' "legacy business" and "TAV [THV] business" and finding that "the TAV [THV] business is the most important growth driver")].

C. Medtronic CoreValve's Blatant Disregard for the Patent System

1. Edwards and Medtronic CoreValve Are Direct Competitors in THV

At the time of trial, Medtronic CoreValve was Edwards' only competitor in the THV market. [D.I. 328 at 514-15, 566-67]. Although several new competitors have entered the

market abroad, none has had a significant impact on the worldwide commercial THV market. [Decl., Ex. B at 43-44, 46-48; Ex. C at 4 ( )]. No other competitor is expected to enter the U.S. THV market before the '552 Patent expires in 2016. [Wood Decl. ¶ 17].

2. Medtronic CoreValve Willfully Infringed, Ignored the Verdict, and

In April 2005, Edwards sent a warning letter to Medtronic CoreValve's founder Dr. Seguin, citing the '552 Patent. [D.I. 330 at 1234-36, 1239-40]. Dr. Seguin never replied. [*Id.*]. But in a call with financial analysts three months later, he recognized the '552 Patent as a "very strong patent." [D.I. 330 at 1240-43]. Yet he and Medtronic CoreValve marched ahead. Medtronic CoreValve knew there was a [Decl., Ex. D at 206].[5] But Medtronic CoreValve never before the verdict. [Decl., Ex. E]. Medtronic CoreValve's public statements about having manufacturing capability outside the U.S. were [Decl., Ex. D at 226-28]. Even after the willful infringement verdict, Medtronic's CEO touted the infringing product on CNBC as Medtronic CoreValve's "innovation." [D.I. 358, Egan Decl., Ex. 18].

Nearly four months after the verdict, Medtronic CoreValve complained that [D.I. 392 at 6]. Its difficulties were self-imposed. [Decl., Ex. W at 22, 24 (admitting Medtronic CoreValve made a because

[5] In 2012, Edwards received this discovery into Medtronic CoreValve's post-verdict manufacturing in a separate action for infringement of Edwards' Cribier *et al.* U.S. Patent No. 8,002,825. *Edwards Lifesciences LLC* v. *Medtronic CoreValve LLC*, C.A. No. 12-23-GMS (D. Del.) ("*Cribier Delaware*"). The parties agreed that discovery in *Cribier Delaware* is deemed produced in this case (*Edwards I*). [D.I. 450 at 1].

[redacted]); Ex. K at 245 (admitting [redacted])].

Instead of respecting Edwards' patent rights, Medtronic CoreValve made [redacted] infringing devices in the U.S. It told employees that [redacted] [Decl., Ex. F; Ex. D at 337-38]. It increased infringement [redacted]. [Decl., Ex. Q at MEDCORE 113211]. Medtronic CoreValve submitted several declarations to this Court about moving to Mexico [D.I. 393, A431-35, A662-64], but it never acknowledged that its first priority was to produce [redacted] ReValving devices in the U.S. for as long as possible. As Medtronic CoreValve now admits, it [redacted]" [Decl., Ex. W at 18]. It simply chose not to.

Medtronic CoreValve remains in the U.S. As it recently admitted: [redacted] [Decl., Ex. D at 334]. Medtronic CoreValve's [redacted] [*Id.* at 249-50].

3. Three Years Later, Medtronic CoreValve Still Makes Infringing Products in the U.S.

Since the verdict three years ago, Medtronic CoreValve's statements about moving to Mexico have been, at best, misleading. *See* Appendix A (collecting statements). [redacted] [*Cribier Delaware*, D.I 77, 91]. And, since the verdict,

it also makes [redacted].[6] [*Cribier Delaware*, D.I. 76, Ex. 1 at ¶¶ 14-15].

4. Medtronic CoreValve Uses [redacted]

Since the verdict in April 2010, Medtronic CoreValve has made [redacted]. [Decl., Ex. G]. Medtronic CoreValve's plan includes [redacted] [Decl., Ex. D at 319 [redacted]

5. Medtronic CoreValve Is Already Selling in the U.S. and Plans a [redacted]

Medtronic CoreValve is also taking sales from Edwards in the U.S. While Edwards' SAPIEN device was approved by the FDA as safe and effective [Decl., Exs. H and I], Medtronic CoreValve's ReValving products have not yet received FDA approval. [Decl., Ex. B at 38-39]. Medtronic CoreValve is participating in numerous U.S. clinical trials. [Decl., Ex. J at 2]. But

[6] This § 271(f) infringement of the '552 Patent is at issue in *Edwards Lifesciences* v. *Medtronic CoreValve, LLC*, C.A. No. 09-873 (GMS) (D. Del.) ("*Edwards II*"). Edwards does not seek to enjoin such activities in the present case (*Edwards I*).

after completing clinical trial enrollment, Medtronic CoreValve also is [redacted]. [*Id.*; Decl., Ex. B at 78-79, 98-99]. Medtronic CoreValve expects FDA approval [redacted]. [Decl., Ex. B at 38-39, 195-96].

V. ARGUMENT

A. The Right to Injunctive Relief

"[T]he axiomatic remedy for trespass on property rights is removal of the trespasser." *Presidio*, 702 F.3d at 1362. Equity sets forth the relevant four-factor test: (1) irreparable harm, (2) inadequacy of remedies at law, (3) balance of hardships, and (4) the public interest. *eBay*, 547 U.S. at 391-92. "This analysis proceeds with an eye to the 'long tradition of equity practice' granting 'injunctive relief upon a finding of infringement in the vast majority of patent cases.'" *Presidio*, 702 F.3d at 1362 (quoting *eBay*, 547 U.S. at 395 (Roberts, C.J., concurring)). "While a patentee is not entitled to an injunction in every case, 'it does not follow that courts should entirely ignore the fundamental nature of patents as property rights granting the owner the right to exclude.'" *Id.* at 1363 (quoting *Robert Bosch*, 659 F.3d at 1149). In addition, an infringer's avowed cessation of infringement "is generally not a reason for denying an injunction against future infringement." *W.L. Gore & Assocs., Inc.* v. *Garlock, Inc.*, 842 F.2d 1275, 1281-82 (Fed. Cir. 1988); *I-Flow Corp.* v. *Apex Med. Techs., Inc.*, No. 07cv1200 DMS (NLS), 2010 WL 141402, at *1 (S.D. Cal. Jan. 8, 2010) (granting injunction even after infringing manufacturing ceased). "Absent adverse equitable considerations, the winner of a judgment of validity and infringement may normally expect to regain the exclusivity that was lost with the infringement." *Edwards*, 699 F.3d at 1314.

B. Irreparable Harm

1. Edwards Practices Its Invention and Is a Direct Competitor with Medtronic CoreValve in THV

"The essential attribute of a patent grant is that it provides a right to exclude competitors from infringing the patent." *Acumed*, 551 F.3d at 1328. "'Courts awarding permanent injunctions typically do so under circumstances where plaintiff practices its invention and is a direct market competitor.'" *Edwards*, 699 F.3d at 1315 (quoting *Advanced Cardiovascular Sys.* v. *Medtronic Vascular, Inc.*, 579 F. Supp. 2d 554 (D. Del. 2008)). Indeed, "[d]irect competition in the same market is certainly one factor suggesting strongly the potential for irreparable harm without enforcement of the right to exclude." *Presidio*, 702 F.3d at 1363.

Here, Edwards' SAPIEN product practices the '552 Patent. Edwards marks the '552 Patent on its SAPIEN packaging. [D.I. 438 at 493]. Edwards paid the inventors royalties on the SAPIEN THV. [*Id.*]. Edwards' trial expert Dr. Nigel Buller, whose infringement analysis the jury accepted, testified that the SAPIEN product is an embodiment of the '552 Patent. [D.I. 329 at 807]. His testimony was unchallenged.

Further, Edwards and Medtronic CoreValve are direct competitors in the same market. *See* Section IV.C.1., *supra*. No other competitors have a significant impact on the commercial THV market. *Id.* And Edwards and Medtronic CoreValve are the only potential competitors in the U.S. THV market through the life of the '552 Patent. The THV market is unlike the typical market for consumer goods, where competitors compete for each consumer sale, and the competition is instantaneous and ongoing.[7] Competition for THV sales is not on a unit-by-unit basis, but rather is characterized by competing to train doctors and establish hospital accounts.

[7] Courts have recognized that market structure is important to irreparable harm. *See, e.g.*, *Broadcom*, 543 F.3d at 702-03 (affirming injunction given the "structural nature" of competition in the chipset market for mobile radio devices); *i4i*, 598 F.3d at 862 (affirming injunction where "the infringing acts significantly change[d] the relevant market").

[Wood Decl. ¶ 19]. With rare exceptions, doctors and hospitals choose which THV device to use, not the patients themselves. [*Id.*]. Doctors, once trained, typically stick with the products with which they are familiar. [*Id.* ¶ 20]. And hospitals, once they invest the staff time and resources to begin a THV program, stick with that THV product. [*Id.*]. Such "stickiness" on the part of doctors and hospitals ensures that the past loss of opportunities to train doctors and sign up hospitals results in future, irreparable harm, including loss of market share, brand recognition, and consumer goodwill. [Declaration of Dr. Gregory Leonard ("Leonard Decl.") ¶¶ 3-7].[8]

Through its aggressive willful infringement in Irvine, Medtronic CoreValve reached many doctors and hospitals before Edwards had a product on the market. [D.I. 328 at 515]. Edwards continues to lose sales at many hospitals Medtronic CoreValve reached first. [*Id.* at 586; Decl., Ex. Y]. Edwards and Medtronic CoreValve also compete to make initial sales to hospitals that have yet to adopt either product. [D.I. 328 at 587-89; Wood Decl. ¶¶ 26, 28, 29]. Where, as here, the patentee and adjudged infringer both practice the patented technology, an injunction is "particularly apt." *Robert Bosch*, 659 F.3d at 1149-50.

2. Medtronic CoreValve Sells Infringing ReValving Products in the U.S.

Despite the verdict of willful infringement, Medtronic CoreValve is [redacted]. [Decl., Ex. B at 78-79, 98-99]. The company has [redacted]. [Decl., Ex. P]. Medtronic has an active website advertising [redacted] hospitals and the principal doctors. [Wood Decl., Ex. 3].

[8] Courts have encountered this "stickiness" problem before and have granted injunctions to address the irreparable harm involved. *See, e.g.*, *TiVo Inc.* v. *EchoStar Commc'ns Corp.*, 446 F. Supp. 2d 664, 669-70 (E.D. Tex. 2006), *aff'd in part*, *rev'd in part*, *remanded in part* 516 F.3d 1290 (Fed. Cir. 2008); *Atlanta Attachment Co.* v. *Leggett & Platt, Inc.*, No. 1:05-CV-1071-ODE, 2007 WL 5011980, at *7 (N.D. Ga. Feb. 23, 2007); *see also Acumed*, 551 F.3d at 1328-29 (approving reliance on *TiVo*).

Edwards already is being harmed by Medtronic CoreValve's presence in the U.S. market. Numerous U.S. hospitals with ReValving accounts [redacted]. [*See* Declarations of Roger Riggs, Patrick Brady, and Richard Carey; Wood Decl. ¶¶ 29-30].

In addition, Medtronic CoreValve plans a [redacted] in the U.S. [redacted]. The harm Edwards would suffer is incalculable. When Medtronic acquired CoreValve, Inc., it boasted that its "scale and expertise" would "accelerate the use" of the infringing ReValving products. [D.I. 358, Egan Decl., Ex. 20]. Absent an injunction, that prediction will come true in the U.S. Medtronic, "the world's largest standalone medical technology company," reported $16.2 billion in net sales in 2012 – more than eight times Edwards' net sales ($1.9 billion) over the same time period. [Decl., Ex. N at inside cover, 34; Ex. O at 26]. Medtronic intends to leverage this scale and market power, as well as its relationships with doctors and hospitals, to siphon further THV sales from Edwards. [D.I. 358, Egan Decl., Ex. 20].

Such future injuries are irreparable, particularly given the structure and stickiness of the THV market described above. *See Presidio*, 702 F.3d at 1363 (direct competition in U.S. market "suggest[s] strongly the potential for irreparable harm"). Edwards would continue to suffer price erosion, as Medtronic CoreValve has a [redacted] [Decl., Ex. B at 74-76; Ex. Y at Ex. 5.1]. Expanded commercial sale of Medtronic CoreValve products in the U.S. would dilute Edwards' rightful goodwill and brand recognition as the innovator of the revolutionary THV technology. *See i4i*, 598 F.3d at 862 ("loss of market share, brand recognition, and customer goodwill" are irreparable injuries). An injunction is the appropriate remedy to curb such infringement. *Edwards*, 699 F.3d at 1315; 35 U.S.C. § 283 (authorizing injunctions "to prevent the violation of

any right secured by patent").

3. Medtronic CoreValve Is Making Infringing ReValving Products in the U.S. [redacted]

In addition, Medtronic CoreValve is using ReValving products made in the U.S. to [redacted] and steal sales from Edwards. Well after the verdict, Medtronic CoreValve continued making ReValving products in the U.S. [redacted] [Decl., Ex. D at 258, 318-20]. Medtronic CoreValve admits that [redacted] [Ex. W at 17 n.30]. Without the U.S.-made infringing ReValving products, Medtronic CoreValve could not have [redacted]. Medtronic CoreValve chose to take those sales from Edwards – as it admits. [*Id.* at 56 [redacted])].

Medtronic CoreValve intends to keep infringing [redacted]. [Decl., Ex. D at 319 [redacted] Ex. B at 128; Ex. W at 17 n.30 (March 15, 2013 report) [redacted]]. Given the long-lasting effect of the first-mover advantage in this market, Medtronic CoreValve, a "calculating infringer," is willing "to risk a delayed payment to obtain use of valuable property without prior negotiation or the owner's permission." *Presidio*, 702 F.3d at 1362-63. This harm extends for an unquantifiable period into the future, and is irreparable. [Leonard Decl. ¶ 13].

4. Medtronic CoreValve's Sales of U.S.-Made Devices in Europe Continue to Harm Edwards

As the jury found, Edwards lost a substantial share of the THV market in Europe because

of Medtronic CoreValve's willful infringement. [Verdict, D.I. 313 at 5; *see also* Accounting, D.I. 439 at 1]. As the Federal Circuit has held, evidence of lost sales "squarely supports a finding of irreparable harm." *Presidio*, 702 F.3d at 1363; *see also Robert Bosch*, 659 F.3d at 1152 ("loss of market share" supports a finding of irreparable harm). Edwards also lost opportunities to train doctors and establish hospital accounts, which has caused it to continue to lose access to patients it could treat. [Decl., Ex. Y; Wood Decl. ¶¶ 22-29]. *See Robert Bosch*, 659 F.3d at 1152 ("loss of . . . access to potential customers" supports finding of irreparable harm).

In addition, Medtronic CoreValve trained many doctors in Europe before Edwards. These doctors continue to publish in medical journals, falsely burnishing Medtronic CoreValve's reputation as the THV innovator and harming Edwards' reputation as the global leader in the science of heart valves. [Wood Decl. ¶ 23]. It was Edwards that took the risk, invested [redacted], and successfully proved that Medtronic CoreValve is a willful infringer. Now, the European doctors Medtronic CoreValve trained are teaching U.S. doctors how to use the infringing ReValving products, in an effort to overwhelm Edwards in the U.S. market. [*Id.* ¶ 24].

C. Inadequate Remedies at Law

"It is not enough that there is a remedy at law; it must be plain and adequate, or, in other words, as practical and efficient to the ends of justice and its prompt administration as the remedy in equity." *Acumed LLC* v. *Stryker Corp.*, No. 04-CV-513-BR, 2007 WL 4180682, at *5 (D. Or. Nov. 20, 2007) (granting injunction), *aff'd by* 551 F.3d 1323 (Fed. Cir. 2008). Money damages alone would not meet the ends of justice here. Medtronic CoreValve would continue its willful infringement. And Edwards would not be compensated for immeasurable losses, particularly when Medtronic CoreValve [redacted] U.S. [redacted].

Medtronic CoreValve has made clear that ongoing monetary damages will not deter it

from making and selling infringing ReValving products in the U.S. *See* Section IV.C., *supra*. The unique advantages of making the ReValving products in Irvine were discussed at trial, and not disputed by Medtronic CoreValve. [D.I. 329 at 916-17, 931-33; D.I. 331 at 1330, 1412-14]. Irvine offers a highly specialized labor pool unavailable elsewhere. [D.I. 329 at 931-33].

In the developing THV market, the effect of a compulsory license to a direct competitor extends beyond monetary damages.[9] More than three years after the verdict, Medtronic CoreValve continues to use U.S. manufacturing to gain a head start in [redacted] THV markets. *See* Section IV.C.4., *supra*. If it had honored Edwards' patent rights, Medtronic CoreValve would have to wait [redacted]. *See* 21 C.F.R. § 812.20(b)(3). Instead, Medtronic CoreValve has taken a shortcut, making infringing ReValving products in the U.S. in order to [redacted].

Monetary relief cannot protect Edwards' right to exclude Medtronic CoreValve from the U.S. market. Absent an injunction, the floodgates will open [redacted] when Medtronic CoreValve makes its threatened general U.S. launch. Right now, the U.S. is a nascent THV market, with the first device (SAPIEN) approved for sale only in November 2011 (post-verdict). [Decl., Ex. H]. Adoption of THV in the U.S. is limited by the number of hospitals approved for Medicare compensation. [Wood Decl., Ex. 2 at 1-2]. Edwards is already being forced to compete for sales in the limited number of qualified centers. [*See* Riggs, Brady, Carey Decls.; Wood Decl. ¶¶ 28-30]. Absent an injunction, Medtronic CoreValve will, as more hospitals meet national Medicare coverage requirements for THV, establish new hospital accounts in the U.S.

[9] Although Medtronic CoreValve previously argued that Edwards had licensed the '552 Patent to another competitor, [D.I. 392 at 9-10], the Federal Circuit concluded that "no such license exists." *Edwards*, 699 F.3d at 1315.

and continue to sell itself as a THV pioneer. [Wood Decl. ¶ 28]. Edwards will continue to suffer price erosion and loss of market share and reputation. [Leonard Decl. ¶¶ 10-12]. Only an injunction will prevent Medtronic CoreValve from inflicting these harms on Edwards and protect Edwards' patent rights. *See Robert Bosch*, 659 F.3d at 1155 (granting injunction where "[t]here is no reason to believe [the infringer] will stop infringing, or that the irreparable harms resulting from its infringement will otherwise cease, absent an injunction").

Medtronic CoreValve's infringement has and will continue to cause loss of market share, brand recognition, and customer goodwill. *See* Section V.B., *supra*. As here, "[s]uch losses may frequently defy attempts at valuation." *i4i*, 598 F.3d at 862. [Leonard Decl. ¶¶ 13]. This "difficulty in estimating monetary damages reinforces the inadequacy of a remedy at law." *Broadcom*, 543 F.3d at 703. Indeed, these harms will continue and their impact may never be fully determined. Money simply cannot make Edwards whole.

D. Balance of Hardships

Requiring Edwards "to compete against its own patented invention," with the resulting harms described in Section V.B., *supra*, places "a substantial hardship" on Edwards. *Robert Bosch*, 659 F.3d at 1156. By trial, Edwards had spent over $400 million on the SAPIEN products. [D.I. 438 at 455]. As Mr. Wood testified, Edwards could not afford such investments in medical innovation if "someone could wait until you did all the heavy lifting and did all the design work and then they could just copy your design and bring it to market." [*Id.* at 454].

On the other hand, there is no cognizable hardship to Medtronic CoreValve. Medtronic CoreValve was purchased by Medtronic, Inc., the world's largest standalone medical technology company. Heart valves account for less than 7% of Medtronic's business, but over 70% of Edwards'. [Decl., Ex. N at 34 (Structural Heart 2012 net sales); Ex. O at 26 (2012 net sales)]. Medtronic CoreValve cannot complain if it is barred from making, using, and selling infringing

products in the U.S. "One who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so elected." *Acumed*, 551 F.3d at 1330 (quotations omitted); *i4i*, 598 F.3d at 863 ("[N]either commercial success, nor sunk development costs, shield an infringer from injunctive relief.").

As Medtronic CoreValve represented to the Federal Circuit in January 2012, Medtronic CoreValve "could easily move the rest [of its operations to Mexico] if there were an injunction." [*Cribier Delaware*, D.I. 78, Ex. 5]. Instead, it made a [redacted] to stay in the U.S. and increase its profits. *See* Section IV.C.2., *supra*.

E. Public Interest

"[T]he touchstone of the public interest factor is whether an injunction, both in scope and effect, strikes a workable balance between protecting the patentee's rights and protecting the public from the injunction's adverse effects." *i4i*, 598 F.3d at 863. Edwards has submitted a proposed order concurrently with this brief. This proposed order ensures that no patient who otherwise could receive an Edwards or Medtronic CoreValve THV device will be barred from treatment.

1. FDA Concluded Edwards' SAPIEN Products Are Safe and Effective

In Europe, a medical device receives CE Mark approval if it "is basically safe" and "it performs as you say it will perform." [Decl., Ex. X at 118-19]. In the U.S., a more demanding standard applies, with the FDA requiring proof that the device is safe and effective compared to alternative treatments. [*Id.*; D.I. 438 at 475-76]; 21 C.F.R. § 814.

To date, only Edwards' SAPIEN products have received FDA approval. *See* Section IV.C.5., *supra*. After reviewing the evidence, the medical experts at the FDA determined that Edwards' SAPIEN products are safe and effective. [Decl., Exs. H and I]. Despite the fact that Medtronic CoreValve's ReValving 26 and 29 mm products and Edwards' SAPIEN products all

received CE Mark approval in 2007 [D.I. 328 at 565-66], Medtronic CoreValve's ReValving products still have not met the higher bar of FDA approval. [Decl., Ex. B at 38-39].

2. The Proposed Injunction Does Not Disserve Patients Yet Protects Edwards' Patent Rights

Within the U.S.: Currently, Edwards' SAPIEN products are approved for U.S. sale. [Decl., Exs. H and I]. The FDA has not approved any of Medtronic CoreValve's ReValving products. [Decl., Ex. B at 38-39]. The proposed order enables Medtronic CoreValve to continue its feasibility and/or pivotal clinical trials [Proposed Order ¶ 2], and to treat the few patients that Edwards cannot [*id.* ¶ 3]. The proposed injunction will not disserve the public interest.

Outside the U.S.: In countries that require U.S.-made devices, Edwards' proposed injunction also allows Medtronic CoreValve to treat the few patients that Edwards cannot. [*Id.* at ¶ 3]. For the remaining countries outside the U.S., Medtronic CoreValve has represented that [redacted]. [Decl., Ex. D at 279-80; *accord id.* at 278 [redacted]].

In sum, the public interest would be served by the proposed injunction. Edwards' proposed order, which carves out the limited patients it cannot treat, "strikes a workable balance between protecting the patentee's rights and protecting the public from the injunction's adverse effects." *i4i*, 598 F.3d at 863.

VI. CONCLUSION

For these reasons, Edwards respectfully requests that the Court grant Edwards' motion for a permanent injunction.

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April 24, 2013

CERTIFICATE OF SERVICE

I hereby certify that on April 24, 2013 I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on April 24, 2013 upon the following in the manner indicated:

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APPENDIX A

Appendix A to Edwards' Opening Brief in Support of Its Motion for a Permanent Injunction: Chronology of Statements about Moving to Mexico

Date	Statement	References
April 1, 2010	Verdict of literal, willful infringement.	D.I. 313.
April 1, 2010	Medtronic, Inc. press release: "In the event of a US injunction, Medtronic has manufacturing capabilities for CoreValve products outside the United States to ensure continued supply world wide."	D.I. 358, Egan Decl., Ex. 21 at 1.
April 5, 2010	Bank of America Merrill Lynch report: "MDT is in the process of moving manufacturing for CoreValve's European business to Mexico. . . . MDT is implying they can begin to ship from Mexico within a month or two although today they have not started manufacturing there."	D.I. 358, Egan Decl., Ex. 22 at 1.
July 12, 2010	Medtronic CoreValve's reply brief in support of its motion to stay or alternatively partially dismiss *Edwards II*: "CoreValve's plan to move manufacturing of the ReValving System to Mexico is hardly 'new activity.'"	*Edwards II* (C.A. No. 09-873 (GMS)), D.I. 20 at 1.
July 26, 2010	Medtronic CoreValve's answering brief in opposition to Edwards' motion for a permanent injunction: [redacted]	D.I. 392 at 6.
March 21, 2011	Medtronic CoreValve accounting statement: "… CoreValve Generation 3 devices that have been manufactured in the United States for commercial sale, but which have not been sold."	D.I. 439 at 4.

Date	Statement	References
August 8, 2011	Medtronic CoreValve Federal Circuit brief: [redacted]	Declaration of Christopher Terranova in Support of Edwards' Motion for Enhanced Post-Verdict Damages and Post-Verdict Attorneys' Fees ("Terranova Decl."), Ex. 14 at 43, 46.
January 11, 2012	Medtronic CoreValve Federal Circuit argument: "CoreValve has moved 60% of its operations to Mexico and could easily move the rest if there were an injunction."	Terranova Decl., Ex. 16.
November 13, 2012	Federal Circuit decision: "CoreValve does not deny[ ] that CoreValve never stopped its infringing manufacture in California. Whether or not that representation was known to be false when made, the situation before us reflects, at least, changed circumstances."	*Edwards* v. *CoreValve*, 699 F.3d 1305, 1315 (Fed. Cir. 2012).
November 30, 2012	Medtronic witness James Sparks: [redacted]	Terranova Decl., Ex. 12 at 343:23-24; *see also id.* at 215:20-25.
February 6, 2013	Medtronic CoreValve's motion to stay Federal Circuit mandate: "Complying with a permanent injunction would impose substantial and irreversible harm on CoreValve by requiring relocation of its manufacturing operations outside the United States . . . ."	Terranova Decl., Ex. 3 at 4.
February 22, 2013	Medtronic CoreValve's counsel during teleconference with Court: [redacted]	Terranova Decl., Ex. 15 at 8:10-11.
March 8, 2013	Medtronic CoreValve's renewed motion to dismiss *Edwards II*: "… Medtronic has moved virtually all commercial manufacture of the ReValving product to Mexico."	*Edwards II*, D.I. 25 at 4.

Date	Statement	References
March 15, 2013	Medtronic CoreValve Expert Report of John R. Bone: [redacted]	Terranova Decl., Ex. 13 at 17-18, 56 n.119; *accord id.* at 17 n.30; *see also* Ex. 3.2 to the same report.
April 17, 2013	Medtronic CoreValve Expert John R. Bone's deposition: [redacted]	Terranova Decl., Ex. 29 at 187:21-25; 215:19; 219:22; 261:20-22.

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